

REMARKS**I. Disposition of claims**

Applicant filed a Preliminary Amendment currently with the application on 19 December 2005. Claims 4 and 6 were canceled. Accordingly, claims 1-3, 5, 7 and 8 are pending. It appears from the Office Action that the Examiner may not have considered the Preliminary Amendment when issuing the Office Action.

II. Claim rejections – 35 U.S.C. §§101 and 112

The cancelation of claim 6 renders moot the rejection of record under 35 U.S.C. §§101 and 112, second paragraph. Withdrawal of the claim rejections is requested.

III. Claim rejections – 35 U.S.C. §103

Claims 1-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,313,137 to Amin et al. ("Amin"). For the reasons given on pages 4-5 of the Office Action, the Examiner alleges that it would have been obvious to make a similar salt having a similar therapeutic effect based on the disclosure provided by Amin.

Applicant submits herewith a Declaration under 37 C.F.R. § 1.132 (hereinafter the "Declaration") in the name of the inventor, Peter Nordberg. The Declaration supplements the dissolution data appearing at pages 17-18 of the application by providing a comparison of the solubility, in fasted state simulated intestinal fluid (FaSSIF), of the claimed compound with the compound of Example 1.3 of Amin:

| Structure | Compound | Solubility μM 1 h | Solubility μM 24 h | Solubility μM 24 h (base form) |
|-----------|---|----------------------|-----------------------|--------------------------------------|
| | Present inv. (Mesylate salt) | 279 | 218 | 48 |
| | Example 1.3 of Amin (Mesylate salt) | 19 | 17 | 13 |

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The Declaration demonstrates an unexpected and superior dissolution behavior of the claimed compound as compared to that of Example 1.3 of Amin. As is apparent from the comparative data, the solubility of the base form and myslate salt of the claimed invention, measured after 24 hours, was 48 $\mu\text{mol/l}$ and 218 $\mu\text{mol/l}$, respectively. In contrast, the solubility of the base form and myslate salt of the compound of example 1.3 of Amin, measured after 24 hours, was 13 $\mu\text{mol/l}$ and 17 $\mu\text{mol/l}$, respectively.

The above biological test data demonstrates a superior unexpected result that is not suggested by Amin. It is precisely this type of "greater than expected result" which has long been an evidentiary factor pertinent to a finding of nonobviousness. (*United States v. Adams*, 383 U.S. 39, 51-52 (1966)). Withdrawal of the §103 rejection is requested.

CONCLUSION

Claims 1-3, 5, 7 and 8 are pending. In view of the comparative data set forth in the Declaration submitted herewith, Applicant submits that the application is in condition for allowance.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: 22 August 2008

Respectfully submitted,

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